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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,565	10/19/2001	Yuusuke Nonomura	871A 3068	7124

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EXAMINER

ROSE, SHEP K

ART UNIT

PAPER NUMBER

1614

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10 038565

Applicant(s)

YUUSUKU DONOMURA, et al

Examiner

S HOP ROSE

Group Art Unit

1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1, 5, 18 is/are pending in the application.
- Of the above claim(s) 2, 4, 8, 18 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 5, 6, 7 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claim(s) 1, 5, 18 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

Applicants have filed application Serial No. 10/038,565 on October 19, 2001 with 18 composition claims and two sheets of drawings, (Figures 1 and 2) and claim an October 20, 2000 Japanese priority date.

The Specification is objected to as it fails to include, any page one (it starts on page 2), or any separate paragraph entitled "Brief Description of the Drawings". According to the recitals of the bottom 5 lines of page 12 of the Specification, Figure 1 is the chemical structure of amphotericin B antifungal agent, while Figure 2 is the chemical structure of azithromycin antibiotic.

Figures 1 and 2 are objected to for failing to contain these captions.

The eighteen composition claims recite plural active agent species and are improperly indefinite and alternative in each recitation of "or" and "such as", which appears in line 1 of claims 1, 2, and 3. Moreover, claims 8 to 11 improperly recite "in any of claim 1 through claim 5."

The most comprehensive active agent species composition claims are to the combination of amphotericin B antifungal agent (claim 5) with azithromycin antibiotic (claim 7), which are constructively elected by original presentation, for oral dental or periodontal treatment.

Page 4 of the specification indicates that a "first example" is a medication consisting of amphotericin B ("Halizon") of Fig. 1 and azithromycin ("Zithromax") in Fig 2 as its components, for treating periodontitis.

Pages 5 and 6 (top 6 lines) indicate "variations of the "first example" to include denture disinfections of Candida growth.

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Pages 6 to 9 indicate plural combined anti-bacterial antifungal agent species: A1, A2, B1, B2, C1, C2, D1, D2, E1, E2, F1, F2 and G as 2, 3, and 4 product mixes, mentioning the addition of other antifungal agent species: metronidazole (Flagyl), fluconazole (Diflucan) and miconazole, in addition to amphotericin B, to anti-bacterial antibiotics, including tetracycline, penicillin, "Kefral" cephem-type, "ciproxan" ciprofloxacin, in addition to azithromycin ("Zithromax") antibiotic, all of which combinations are encompassed by the broad terms of claim 1 "an antifungal agent and an antibiotic".

Pages 9 and 10 relate to a "Second Example" which adds plural species of known agents to be used with the medicines of the first example, while pages 10 and 11 list plural species of carriers, page 12 lists more possible uses, and page 12 possible new antibiotic synthesis, while claims 2 to 4, 8 to 18 recite one or more of these further plural active agent and plural carrier species.

As noted above, while applicants' first example consists of amphotericin B (antifungal agent) and azithromycin (antibiotic) there is no claim presented corresponding thereto. None of the eighteen composition claims recite consisting of, and (as noted above) the first 3 claims recite "such as".

Claims 5 and 7, and claims 1 and 6, generic thereto, call for a composition comprising (A) amphotericin B, or another antifungal agent, and (B) azithronycin, or another antibiotic, or another macrolide antibiotic, in any proportions of (A) to (B), to treat species of bacteria and species of fungi sensitive to (A) and to (B) not only in the periodontal pockets, but also as encountered in dental oral care, in the region of dental

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carries lesions, in dental pulp, in the presence of persistent pus discharge and biofilm, root canal, bone infection and also to treat candida growth in denture wearers with tooth and dental root carries and periodontosis.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5, 6, 7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over each of:

Brizzolari et al (I) (claims 2 and 22, column 2, lines 36 to 59, column 8, lines 45 to 53) periodontal mixture of encompassed species of antibiotics and antifungal agents;

Brizzolara et al (II) (claim 8, column 2, lines 13-34) periodontal mixture of encompassed species of antibiotics and antifungal agents;

Dunn (column 9, lines 11 to 20) periodontal treatment with encompassed species of antifungal agents, like mystation metronidazole, and plural encompassed species of antibacterial antibiotics.

Rajaiah et al (I-II) (claim 17) denture adhesives with mixtures of encompassed species of antibiotics and antifungal agents,

Little et al, identifying and treating oral individual and mixed flora candida and other fungus species infections and bacterial infections with individual and mixtures of amphotericin B, and other anti-fungal agents: mystatin, azoles, griseofulvin (column 11, lines 1 to 67) and anti-bacterial antibiotics including azithromycin (column 12, lines 31, 38, to column 15, line 51) after first identifying the pathogenic species of fungi and of bacteria (See the entire document);

Brockbank et al, (not an oral treatment agent) as antibiotic “cocktail” of antifungal agents: amphotericin B and fluconazole, and encompassed plural species of antibacterial antibiotics, to substantially inhibit both fungal (especially candida) and bacterial growth, (see especially, columns 1 to 3, 24 to 28 and claim 1;);

Ayon-Covarrubias, including encompassed species of antibiotics, like gentamycin, into dental use antifungal treatment of Candida composition, with encompassed species of antifungal agents, (see claims 2, 3, 9, and column 2, lines 11 to 13, 62, and column 3, lines 8.

The statement of intended use in the preamble of composition claims 1, 5, 6 and of does not render it patentable, In re Sinex 135 USPQ 302, 305; In re Zierden, 162 USPQ 102, 104, In re Person, 181 USPQ 144.

Claims 1, 5, 6, 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Little et al (details as noted above) in view of which the specific combination consisting of (A) amphotericin B antifungal agent and (B) Azithromycin antibacterial antibiotic

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would be immediately envisioned, once tests established the presence of both pathogenesis fungi species as well as pathogenic bacteria species susceptible to (A) and to (B). In re Kerkhoven, 205 USPQ 1069, 1072.

From the teaching of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

This application contains no allowable generic claim and claims to plural patentably distinct species.

Claims 1 to 18 are generic to a plurality of disclosed patentably distinct species comprising

One ultimate disclosed species of:

- (a) An antifungal agent, such as amphotericin B (claim 5)
- (b) an antibacterial antibiotic, such as azithromycin (claim 7)
- (c) (If further elected) a third further inducing agent species (of claims 14, 15, 16)
- (d) a (If further elected) a second further antifungal agent
- (e) a (If further elected) a second further antibacterial antibiotic
- (f) a (if further elected) a prosthesis component (claims 10, 17, 18)
- (g) (if further elected) nitrogen inclusion (claim 4)
- (h) (if further elected) a species of membrane for periodontum rebuilding (claims 8, 12, 13).

(i) (if further elected) a species of carrier for one of the claim 11 administration modes.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, of each even though this requirement is traversed. If this application is filed under Rule 371, the legal authority is PCT Rule 13.2, Annex B, Part 1 (f) "Markush Practice"; PCT Rule 13 and 35 U.S.C. § 372, rather than 35 U.S.C. § 121.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under U.S.C. § 103 (of) the other invention.

Election of species is required per MPEP § 803, 809.02 (d) (Markush group claim practice, separate and burdensome fields of search required).

Patentably distinct Markush species are independent inventions, In re Webber, 198 USOQ 328, In re Haas, 198 USPQ 334. Divisional applications may be filed under 35 U.S.C. § 121, as a result of an Office requirement for an election of a patentably distinct species as made herein. In re Joyce, 115 USPQ 412, In re Herrick, 115 USPQ 412. This satisfies the "patentably distinct" criterion since the Examiner is not of the opinion that the various species are obviously unpatentable over one another, and each

species (as noted above) is capable of independent manufacture, use and sale, with the other components of the claimed formulations.

Applicant is further required to identify the claims that correspond to the elections as well as those that do not even if the requirements are traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



SHEP K. ROSE
PRIMARY EXAMINER
GROUP 1200

Rose/LR
June 27, 2002